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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,904	01/16/2004	Eric J. Beckman	02-012	1518

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/759,904	Applicant(s) BECKMAN ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15, 16, 18-39 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16, 18-39 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment to the claims filed 12/21/2006 has been entered. Any rejections not addressed in the office action below have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,10-12,19-22,27,34-35 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Liptova et al. (Macromol. Symp. 152,139-150 (2000), cited by applicant), for the reasons set forth in the office action dated 09/21/2006. A new rejection for claim 11 was necessitated by amendment.

Regarding claim 11 the examiner notes that applicants have narrowed the breath of the claim so that some species have been canceled such as carbohydrates, viral vectors, prions ect. Liptova does anticipate a carbohydrate bioactive (heparin) but heparin also anticipates an anticancer agent as evidenced by the teaching of Niers et al. (Mechanisms of heparin induced anti-cancer activity in experimental cancer models, Crit. Rev. Oncol./Hematol. (2006), doi:10.1016/j.critrevonc.2006.07.007). Neirs clearly notes that heparin demonstrated anti-cancer activity in animal tumors, thus heparin

meets the limitation that the bioactive agent is an anticancer agent. See entire document.

Applicants arguments/remarks filed 12/21/2006 have been fully considered but are not considered persuasive.

Applicant asserts that Lipatova does not disclose or suggest that heparin itself is released into the body upon degradation of the polymer but heparin would be incorporated within degradation fragments and would not be released as a result of degradation.

The relevance of this assertion is unclear. Firstly applicants did not disclose were to find the passage within Lipatova that the heparin would be incorporated within the degradation fragments, the examiner could not find this disclosure within the reference, thus applicants have not met their burden of showing that the heparin bond to the polymers within Lipatova would be incorporated within the degradation fragments of the polymer and not released into the body by itself. Since there is no experimental data that supports applicants viewpoint or a disclosure of evidence to the contrary the examiner believes that the heparin could degrade without being connected to the other degradation products through hydrolysis, therefore the limitation is considered met by the examiner. Further the claims as currently amended do not preclude that the bioactive agent would not be incorporated within degradation products, the claims as currently amended only state that the composition is biodegradable within a living organism to biocompatible degradation products including the bioactive agent, the transitional term "including", which is synonymous with "comprising", "containing", or

Art Unit: 1618

"characterized by", is inclusive or open ended and does not exclude additional elements in the prior art. Thus the claim language does not preclude that the bioactive could be connected to degradation products. Furthermore the limitation that the polymer is biodegradable within the body and the released bioactive agent affecting at least one of biological activity or chemical activity in the host organism is an intended use of the polyurethane, ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81. Therefore since the polyurethane is synthesized in the same way is useful as an implant and is the same composition as applicants currently claimed polyurethane composition the limitations in the claims are met. Lastly since the claimed polyurethane composition is the same as applicants currently claimed invention any composition with the same composition as applicants claimed invention would inherently have the same degradation properties when inserted into the body.

Claims 1-4,7-8,12,19,22,27-30,33 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1, cited by applicant), for the reasons set forth in the office action dated 09/21/2006.

Applicants appear to state that as currently amended Woodhouse does not anticipate the claimed invention because amino acids are not included in the Markush group of independent newly amended claims 1,27 and 69.

The relevance of this assertion is unclear, clearly Woodhouse discloses that the amino acid group may be joined together to form an oligopeptide, which would meet the limitation that the bioactive agent is a peptide or a polyamino acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-16, 18-39 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258, cited by applicants), for the reasons set forth in the office action dated 09/21/2006.

Applicants assert that Liptova does not cure the deficiencies of Zhang in which applicants assert does not disclose covalent attachment of a protein or any other bioactive group to the polyurethane. Furthermore applicants assert that Lipatova does not disclose or suggest that heparin itself is released into the body upon degradation of the polymer and that heparin is not a protein but a glycosaminoglycan.

Firstly the examiner acknowledges the misprint/mistake in the previous office action that heparin is a protein, indeed heparin is a glycosaminoglycan but heparin is still obviously a bioactive agent because it is a glycosaminoglycan, glycosaminoglycans are polysaccharides and polysaccharides are carbohydrates, which as claimed by applicants are bioactive agents. From the above arguments Liptova does disclose a heparin containing polyurethane in which the bioactive would be released into the body

Art Unit: 1618

upon degradation of the polymer. Lastly even if Zhang is not enabling for covalent attachment of proteins on the polyurethane it still would have been obvious to the skilled artisan to combine the disclosures of Zhang and Litova to synthesize a biodegradable polyurethane containing a bioactive agent (heparin) that may be applied as a prosthetic appliance in direct contact with living tissues. The two references are obviously combinable with each other because they are directed to the same general field of endeavor, polyurethane compositions for the treatment of living tissues.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

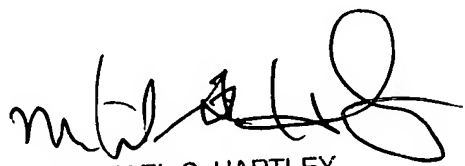
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER